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To cite this article: Alinne Paula de Almeida, Daniela Mayumi Usuda Prado Rocha, Ana Vladia Bandeira Moreira, Hatanne Carla Fialho Moraes e Lima & Helen Hermana Miranda Hermsdorff (2020): Personalized Nutrition Using PROCARDIO to Reduce Cardiometabolic Risk in the Academic Community: A Study Protocol with Preliminary Results, Journal of the American College of Nutrition, DOI: [10.1080/07315724.2019.1706663](https://doi.org/10.1080/07315724.2019.1706663)

To link to this article: <https://doi.org/10.1080/07315724.2019.1706663>



Published online: 26 Feb 2020.



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Personalized Nutrition Using PROCARDIO to Reduce Cardiometabolic Risk in the Academic Community: A Study Protocol with Preliminary Results

Alinne Paula de Almeida^a , Daniela Mayumi Usuda Prado Rocha^a , Ana Vladia Bandeira Moreira^{a,*} ,
Hatanne Carla Fialho Moraes e Lima^b  and Helen Hermana Miranda Hermsdorff^a 

^aDepartment of Nutrition and Health, Universidade Federal de Viosa, Viosa, Brazil; ^bNutrition Section, Health Division, Universidade Federal de Viosa, Viosa, Brazil

ABSTRACT

Background: Strategies of promotion, prevention and health care of individuals with cardiometabolic risk are necessary to control cardiovascular diseases.

Objective: To describe a study design and present partial results of nutritional counseling in the Cardiovascular Health Care Program (PROCARDIO).

Methods: PROCARDIO is a nutritional intervention program for students and workers or dependents of the Brazilian university academic community who are at risk of or have a cardiovascular disease (Brazilian Registry of Clinical Trials n^o RBR-5n4y2g). Patients are submitted to nutritional clinical assessments involving anthropometry, biochemical analysis, sociodemographic and clinical, lifestyle and dietary data. Patients are provided with nutritional counseling, dietetic workshops and educational materials. In addition, nutritional follow-ups are performed monthly.

Results: The sample consisted of 296 patients (171 F/125 M, 27-56 years). The prevalence of individuals with excess body weight, dyslipidemia, diabetes and hypertension in the sample were 74.7% (n = 222), 79.1% (n = 235), 18.2% (n = 54) and 25.3% (n = 75), respectively. After three months of nutritional counseling, PROCARDIO users had decreased body fat, waist circumference, fasting blood glucose, total cholesterol and LDL-C (p < 0.05). Specifically, patients with diabetes exhibited reduced glycated hemoglobin concentrations (p < 0.05); those with dyslipidemia showed a reduction in total cholesterol, LDL-C and LDL/HDL (p < 0.05) concentrations; and those with excess body weight reduced waist circumference, waist-to-hip ratio, body fat, uric acid and total cholesterol/HDL-C ratios (p < 0.05).

Conclusion: PROCARDIO patients concluded with a clinical-metabolic improvement regardless of chronic diseases after receiving nutritional counseling, thus highlighting the importance of individual actions and strategies to be based on personalized nutrition for achieving proposed therapeutic targets.

Abbreviations: ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; NCD: Noncommunicable Diseases; CVD: Cardiovascular Diseases; DM: Diabetes Mellitus; DSA: Health Division; EER: Estimated Energy Needs; BF: Body Fat; AH: Arterial Hypertension; HDL: High-density Lipoprotein; BMI: Body Mass Index; WC: Waist Circumference; US-CRP: Ultra-Sensitive C-Reactive Protein; HC: Hip Circumference; PROCARDIO: The Cardiovascular Health Care Program; WHtR: Waist-to-height Ratio; WHR: Waist-to-hip Ratio; ReBEC: Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaio Clnicos*); SPSS: Statistical Package for Social Sciences; TG: Triglycerides

ARTICLE HISTORY

Received 25 September 2019

Accepted 16 December 2019

KEYWORDS

Cardiovascular diseases;
obesity; diet; weight loss;
uric acid

Introduction

Cardiovascular diseases (CVD) are one of the main public health problems in the world¹, whereas unhealthy dietary patterns, sedentariness, smoking and excessive alcohol consumption are important lifestyle-related risk factors².

In this sense, strategies for controlling cardiometabolic risks combined with nutritional education of high risk individuals may contribute to the decrease of CVD mortality rate^{3,4}. Nutritional counseling should target reducing and controlling body weight, glycemic and lipid profiles, leading to a stabilized health status for patients, thus increasing their quality of life^{5,6}.

A few national and international centers associated with nutritional education aiming to change dietary patterns have provided a strategic, nutritional and therapeutic intervention according to individuals' diseases and needs. These centers also include lectures and discussion groups to improve patients' clinical and metabolic profiles⁷⁻⁹. In this context, counseling strategies provided by telephone or internet have been gaining importance in recent years due to their easy access to health information^{10,11}.

Overall, the aim of the present study was to describe the study design and present partial results of the nutritional

Table 1. The inclusion and exclusion criteria for this program.

| Inclusion | Exclusion |
|--|---|
| <ul style="list-style-type: none"> • Both sexes • Age \geq 20 years • Be a server/dependent or student of Brazilian university • Present CVD diagnosed or occurrence of cardiometabolic risk factors such: • excess weight (body mass index (BMI) \geq 25 kg/m²) • hypertriglyceridemia (triglycerides \geq 150 mg/dL) • hypercholesterolemia (total cholesterol \geq 200 mg/dL) • high-density lipoprotein (HDL) at low concentrations (men $<$ 40 mg/dl and women $<$ 50 mg/dl) • systolic and diastolic blood pressure \geq 130/\geq 85 mmHg or arterial hypertension (AH) diagnosed • glucose fasting \geq 100 mg/DL or Diabetes Mellitus (DM) diagnosed and/or medical record | <ul style="list-style-type: none"> • Children, adolescents and pregnant women • No CVD • No occurrence of cardiometabolic risk factors |

intervention carried out in the Cardiovascular Health Care Program (PROCARDIO).

Methods

Procardio

The Cardiovascular Health Care Program of the Brazilian university community (PROCARDIO) performs a nutritional intervention to promote cardiovascular health and is registered in the Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaio Clínicos* - ReBEC)¹² under the primary identifier number RBR-5n4y2g. The inclusion and exclusion criteria for this program are described in Table 1.

Outcome

The primary outcome expected from this study was body weight and cardiovascular risk reduction. Secondary hypothesized outcomes included a decrease in concentrations of low-density lipoprotein (LDL-C), triglycerides, and glucose, as well as dietary changes such as increased consumption of fruits and vegetables and reduced consumption of saturated fatty acids.

Study design

Members of the Brazilian university academic community who fulfilled the PROCARDIO inclusion criteria were scheduled to visit the Health Division where anthropometric and body composition, clinical and food intake data were evaluated during the first appointment – *first visit*. Primarily, each patient received individual advice and was oriented to return in the following days to perform a biochemistry analysis. Based on clinical-nutritional evaluation, patients' meal plans were composed as a personalized nutritional intervention and delivered up to fifteen days after the first visit - *visit for meal plan presentation*. After thirty days, patients were scheduled for their first return to undergo clinical-nutritional evaluations – *follow-up visits*. Additionally, nutritional practices were reviewed, and subsequent nutritional advice were given when necessary. It is noteworthy that nutritional advice was provided monthly, biochemical and body composition reevaluation occurred every three months, and dietary intake was evaluated every six months. Also, during the intervening period, some activities were carried out (Figure 1). All initial data were reevaluated to assess whether or not a patient could receive nutritional discharge.

Ethics

The research was approved by the Ethics Committee on Human Research from Brazilian University (Ref. number 066/2012/CEPH), in 06/27/2012, according to the resolution 466/2012 of the National Health Council. All participants of the study read and signed the written informed consent form, according to the principles of the Helsinki declaration.

Sociodemographic, clinical and lifestyle data

Data regarding sociodemographic, clinical (sex, age, education, income, marital status, drug use, family disease history) and lifestyle (time of sleep, physical activity and smoking) information were collected using semi-structure questionnaire.

To assess food consumption as well as dietary changes during the intervention, patients underwent a medical history questioning in addition to a 24 h food recall and were also requested to validate food consumption frequency in a semi-quantitative questionnaire for Brazilians¹³. Specific questions about dietary factors associated with increased CVD development risk were also carried out. Dietary intake (calories, macronutrients, fibers, cholesterol, vitamins and minerals) was assessed by the DietPro software using Brazilian Food composition tables, which were quantitatively analyzed using a spreadsheet for each food component (converted to values and expressed in grams).

Anthropometric and body composition evaluation

Weight and height were measured as described by Silva et al. (2015)¹⁴. Body mass index (BMI) was calculated according to the criteria of the World Health Organization (1998)¹⁵ and Lipschitz (1994)¹⁶.

Waist circumference (WC) was measured from the umbilical scar in the horizontal plane¹⁷. Abdominal obesity was considered as WC greater than or equal to 80 cm and 90 cm for women and men, respectively¹⁸. Hip circumference (HC) was measured from the largest proportion of the gluteal region. Waist-to-height ratio (WHtR) and waist-to-hip ratio (WHR) were also calculated. WHtR and WHR were classified as high risk for CVD when \geq 0.5 (both sexes); 0.85 (women) and 1.00 (men)^{19,20}.

Total body fat (BF%) was evaluated by tetrapolar electrical bioimpedance analysis, performed with standard protocol²¹. Obesity was diagnosed according to cutoff points proposed by Bray et al. (2008)²²: $>$ 33% and 25% for women and men, respectively.

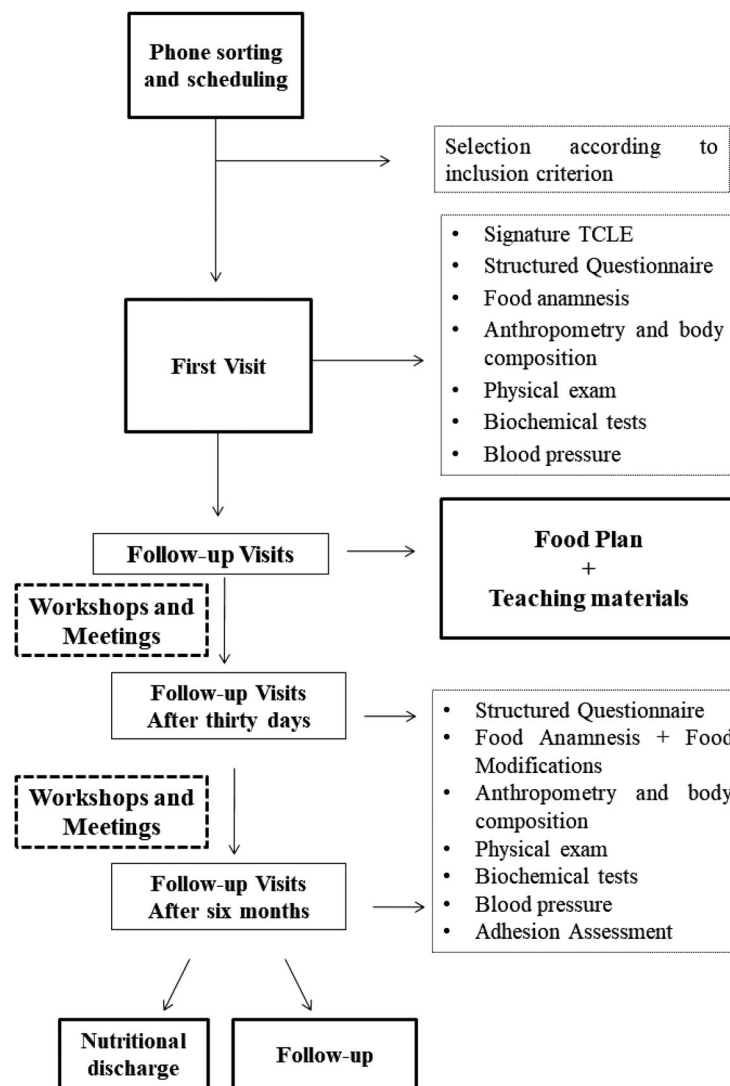


Figure 1. Schematic representation of nutritional intervention PROCARDIO.

Clinical and metabolic evaluation

Metabolic markers were performed at the Clinical Analysis Laboratory of the Brazilian university, according to validated and standardized protocols. The following metabolic variables were analyzed: iron metabolism markers (complete blood count and ferritin), inflammatory markers (complete white blood cell count, platelets and ultra-sensitive c-reactive protein – US - CRP), glucose metabolism (fasting glucose, glycated hemoglobin and insulin), protein metabolism (uric acid, urea and creatinine), lipid metabolism (triglycerides, total cholesterol and lipoprotein fractions - LDL-C, HDL-C and VLDL - very-low-density lipoprotein), and the liver function (alanine (ALT) aminotransferase and aspartate (AST) aminotransferase).

Systolic and diastolic blood pressure were measured and classified as described in the VII Brazilian Hypertension Guidelines (2016)²³.

Nutritional therapy and counseling

Nutritional counseling was carried out according to a clinical-nutritional diagnosis of each participant. Thus, caloric intake

was calculated according to estimated energy requirements (EER) and the physical activity level²⁴. Overweight and obese patients were restricted to caloric intake of 500 to 1000 kcal/day to promote weight loss of around 0.5 to 1.0 kg/week²⁵. The meal plans considered cultural, social and economic aspects as well as food taste and appearance²⁶ (Table 2). Macronutrient distribution (carbohydrate, protein and total fat), fat profile (saturated, monounsaturated, and polyunsaturated fatty acid) and sodium intake were also considered according to individual clinical and metabolic conditions. Lastly, patients received nutritional counseling on food selection, cooking techniques and lists of food substitutions (Table 3).

Nutritional education based on patient participation

Dietetic workshops occurred in the pedagogical kitchen of the Department of Nutrition and Health. Their goals were to educate, raise awareness, exchange dialogue and facilitate the daily life of each patient while also proving that changes in lifestyle and dietary patterns do not necessarily imply restrictions. A discussion group was conducted after the dietary workshops to improve nutritional education.

Table 2. Example of a diet (1500 Kcal) prescribed by the PROCARDIO.

| Meal | Food | Measurement (Calories) | |
|---|--|------------------------------------|----------------------------|
| Breakfast | Whole grain bread | 2 Slices (101 kcal) | |
| | Ricotta cheese | 2 Thin Slices (122 kcal) | |
| | Papaya | 1/2 Unit (60 kcal) | |
| | Tea or coffee (no sugar) | 1 Cup | |
| Collation | Fruit (Apple, pear, banana, plum, nectarine, etc.) | 1 Unit (70 kcal) | |
| Lunch | Raw salad (Lettuce, Watercress, Arugula and other leafy, pepper, green scent, onion, zucchini, cucumber) | No specific amount | |
| | Extra virgin olive oil | 1 Tablespoon (84 kcal) | |
| | Vegetables (choose between chayote, green beans, carrot, beetroot, pumpkin, okra) | 4 Tablespoons (22 kcal) | |
| | White or whole grain rice | 1 Serving spoon (55 kcal) | |
| | Bean | 1 Medium shell (85 kcal) | |
| | Chicken breast – grilled fillet without oil | 1 Medium steak (176 kcal) | |
| | Fruit (Apple ou pear or banana – roasted with cinnamon) | 1 Serving | |
| | Snack | Skimmed fruit yoghurt | 1 1/2 Double cup (70 kcal) |
| | | Nuts or almonds | 4 Units (140 kcal) |
| | Dinner | Whole grain bread | 2 Slices (101 kcal) |
| Ricotta cheese or oil canned tuna | | 1 Slice or 2 tablespoons (55 kcal) | |
| Raw salad (lettuce, watercress, arugula, pepper, parsley, cucumber) | | At least one type | |
| Extra virgin olive oil | | 1 Tablespoon (84 kcal) | |
| Grated Carrot | | 2 Tablespoons (8 kcal) | |
| Supper | Banana | 1 Average unit (88 kcal) | |
| | Granola or oats | 1/2 Cup (168 kcal) | |

Table 3. Meal plan and general guidelines – PROCARDIO.

| Meal plan | |
|---|---|
| Calories and Macronutrients | Recommended Intake |
| Caloric Intake | Customized according to energy needs (Reduction 500-1000 kcal/day for overweight/obesity cases) |
| Proteins | 0.8–1.2 g/kg of Weight |
| Carbohydrates | 45–60% of total caloric intake |
| Fibers | 20–30g/day |
| Fat | 25-35% of total caloric intake |
| Saturated fatty acids | <7% of total caloric intake |
| Polyunsaturated fatty acids | <10% of total caloric intake |
| Monounsaturated fatty acids | 20% of total caloric intake |
| General guidelines | |
| Avoid | Prefer |
| - Skip meals | - Perform all six meals during the day, every three hours. This can help control the appetite and food selection at mealtime. |
| - High-calorie and high-fat foods: soufflés, white sauce, snack foods, stuffed biscuits, ice cream, sautéed and fried foods | - Baked, cooked and grilled preparations and raw salads |
| - Whole milk and dairy products (yoghurt, cream cheese and cream) | - Whole grain foods such as bread, cereals and whole grain or whole wheat pasta |
| - Fatty meats, sausages, viscera, pork and chicken skin, sausages | - Nuts |
| - Butter and lard | - Milk and nonfat dairy products, as well as lean cheese (ricotta and cottage) |
| - Table salt, industrialized sauces, broths or seasonings | - Caution: white cheese does not mean it is not high in fat |
| - Foods that are not included in the eating plan, which can increase intake of calories, sugars and/or fat during the day | - Nuts |
| | - Lean meats: skinless chicken, fish, pork loin and lean beef |
| | -Natural spices such as onions, garlic and chives |
| | - Eat in a quiet environment, chewing food well; this can help with anxiety and reduce food consumption in a meal - Fruits, vegetables, nutrient-dense and low-calorie foods - Always consume plenty of liquids, preferably water |

Note: Table based on Faludi et al. (2017)²⁷.

The PROCARDIO program also offered educational materials, including cookbooks to stimulate healthy cooking and to provide a more dynamical and nutritional approach in food orientation.

Statistical analysis

The collected data are presented in frequency, mean \pm SD and/or in median (25th and 75th percentile), according to variable normality, which was evaluated by the Kolmogorov-Smirnov test.

The variables were classified as followed to perform the appropriate tests: Adults: age < 60 years or Senior: age \geq 60 years. Normal Weight: BMI < 25 and 27 kg/m² for adults and seniors, respectively or Overweight: BMI \geq 25 and 27 kg/m² for adults and seniors, respectively. Normal BF: BF < 25% (women) and 33% (men) or High: \geq 25% (women) and 33% (men). Presence or absence of diabetes, dyslipidemia and hypertension were assessed by self-report.

Table 4. Baseline data of PROCARDIO's patients (n = 296).

| Variables | % (n) |
|--|----------------|
| Age | |
| Adults | 81.0 (n = 240) |
| Seniors | 19.0 (n = 56) |
| Education* | |
| Illiterate/Incomplete Elementary and Middle School | 16.0 (n = 45) |
| Complete Elementary and Middle School | 5.3 (n = 15) |
| Incomplete High School | 1.9 (n = 5) |
| Complete High School | 16.8 (n = 47) |
| Incomplete Undergraduate Studies | 21.8 (n = 61) |
| Complete Undergraduate Studies | 38.2 (n = 107) |
| Link with brazilian university* | |
| Server | 34.2 (n = 101) |
| Student | 40.0 (n = 118) |
| Dependent | 25.8 (n = 76) |
| Own initiative* | |
| Medical Referral | 71.3 (n = 211) |
| Medicine use* | |
| Insulin | 3.1 (n = 9) |
| Antidiabetics | 15.4 (n = 45) |
| Antihypertensives | 40.9 (n = 120) |
| Statins | 31.1 (n = 91) |
| Fibrates | 5.8 (n = 17) |
| Marital status* | |
| Single | 43.4 (n = 128) |
| Married/Stable Union | 48.8 (n = 144) |
| Widow | 3.4 (n = 10) |
| Separated/Divorced | 4.4 (n = 13) |
| Income* | |
| Up to 2 wages | 25.9 (n = 69) |
| 2 to 4 wages | 41.4 (n = 110) |
| 4 to 10 wages | 28.2 (n = 75) |
| More than 10 wages | 4.5 (n = 12) |
| Smokers* | |
| Smokers | 4.1 (n = 12) |
| Physical Activity Practice* | |
| Physical Activity Practice | 52.7 (n = 156) |
| Alcohol Consumption* | |
| Alcohol Consumption | 60.1 (n = 175) |
| Diabetics* | |
| Diabetics | 14.4 (n = 38) |
| Dyslipidemic* | |
| Dyslipidemic | 79.1 (n = 235) |
| Hypertension* | |
| Hypertension | 30.0 (n = 75) |
| Excess Body fat | |
| Excess Body fat | 61.5 (n = 134) |
| Excess body weight | |
| Excess body weight | 74.7 (n = 222) |

*Self-report. Adults: age <60 years. Senior: age ≥ 60 years.

The T-Student test was used to compare the variables of interest with normal distribution among groups divided by gender, age, BMI and total body fat (%). The Mann – Whitney-U test was used to compare the variables of interest that presented non-normal distribution among groups divided by gender, age, BMI and total body fat (%). The Paired T-test was performed to verify a difference in the variables that displayed normal distribution after the three-month nutritional intervention. In this test, all individuals in the sample were evaluated, and divided into groups with based on the presence of diabetes, dyslipidemia or overweight. The Wilcoxon test was utilized to verify a difference in the variables that presented non-normal distribution after the three-month nutritional intervention. In this test, the change was evaluated only for overweight individuals.

Statistical analyses were performed using the SSPS 22.0 program. The level of statistical significance lower than 5% probability was considered.

Partial results

Baseline data

At this moment, all data from 296 patients in the PROCARDIO program (Table 3) have been analyzed.

Considering baseline data, 57.6% (n = 171) of the sample were women and 81.0% (n = 240) were men, with an average age of 43 years (27-56 years). The prevalence of physical inactivity was 47.3% (n = 140), while 71.3% (n = 211) sought the service because of medical referral. Only 4.0% (n = 12) were smokers. Regarding their medical history, 74.7% (n = 222) were overweight (BMI ≥ 25.0 and 27.0 kg/m² in adults and seniors, respectively), while dyslipidemia, diabetic and hypertension patients' prevalence were 79.1% (n = 235), 14.4% (n = 38) and 30.0% (n = 75), respectively (Table 4).

Regarding sex differences, men presented higher values of age, weight, waist circumference, WHR, lean mass, systolic blood pressure, platelets, ferritin, creatinine, uric acid, glucose, TC/HDL, triglycerides and ALT (p < 0.05). However, women showed higher values for BF%, HDL and CRP (p < 0.05). Senior patients presented higher values of waist circumference, WHR, BF%, systolic blood pressure, ferritin, urea and glucose, in addition to low LDL and ALT values (p < 0.05). Overweight individuals and those with excess body fat exhibited higher values for weight, WC, WHR, systolic and diastolic blood pressure, urea, glucose, insulin, CRP and ALT, in addition to minor concentrations of HDL (p < 0.05) (Table 5 - Data Line Base).

Effect of nutritional intervention

After three months of intervention, patients presented decreased BF%, WC, fasting glucose, total cholesterol and LDL-C (p < 0.05) (Figure 2). Diabetics had significant reduction in body weight, waist circumference and glycated hemoglobin (p < 0.05) (Figure 3), while individuals with dyslipidemia reduced in body weight, waist girth, BMI, total cholesterol, LDL and LDL/HDL (p < 0.05) (Figure 4). In turn, overweight individuals decreased in waist circumference, BF%, WHR, triglycerides, fasting glucose and uric acid (p < 0.05) (Figure 5), in addition to reducing TC/HDL ratios (4.7 vs. 4.5; p < 0.05) and total cholesterol (204, 6 mg/dL vs. 198, 9 mg/dL; p = 0,014).

Discussion

The first objective of this work was to describe nutritional counseling strategies developed by PROCARDIO aimed to reduce the cardiometabolic development risk. Previous studies have demonstrated positive results from nutritional interventions during NCD treatment; however, most are focused on only one specific activity for NCD control²⁸⁻³⁴. The nutritional counseling carried out by PROCARDIO covers all activities while also considering personalized diets and dynamic methodologies (educational activities, didactic material supply and internet use) to encourage a healthy lifestyle adoption.

In fact, health educational activities are important strategies to prevent CVD because they can promote lifestyle habit changes and encourage early diagnosis of diseases, thus minimizing the possibility of a disability and the expenses of the health system³⁵. Researchers of an intervention study through a CVD preventive education program

Table 5. PROCARDIO patient portrait according baseline data for sex, age and adiposity indicators.

| Variables | Sex | | Age | | BMI (kg/m ²) | | Total Body Fat (%) | |
|--------------------------|------------------------|-----------------------------------|--------------------|------------------------------------|--------------------------|------------------------------------|--------------------|-----------------------------------|
| | Men (n = 125) | Women (n = 171) | Adult (n = 240) | Senior (n = 56) | Normal Weight (n = 74) | Overweight (n = 222) | Normal (n = 84) | High (n = 134) |
| Age (years) | 45,0 (298,0-57,0) | 41,0 (26,0-56,0)* | – | – | 29,0 (23,8-54,3) | 48,0 (28,0-57,0)* | 28,5 (24,0-49,8) | 51,0 (31,5-59,0) [†] |
| Weight (kg) | 87,5 (75,0-99,5) | 72,2 (61,1-81,5)* | 76,5 (66,6-90,5) | 76,1 (66,0-89,5) | 60,3 (55,3-68,7) | 82,4 (72,5-93,7)* | 71,8 (61,7-80,2) | 85,2 (69,9-95,4)* |
| BMI (kg/m ²) | 29,3 (5,1) | 28,7 (5,6) | 28,7 (5,5) | 29,9 (5,2) | – | – | 25,7 (3,6) | 31,6 (4,7) [†] |
| WC (cm) | 101,0 (13,2) | 94,2 (14,4) [†] | 95,7 (14,4) | 102,2 (12,9)* | 80,6 (8,5) | 102,5 (11,5) [†] | 89,1 (10,8) | 103,6 (12,8) [†] |
| WHR | 0,9 (0,07) | 0,9 (0,09) [†] | 0,9 (0,09) | 0,9 (0,07) [†] | 0,9 (0,09) | 1,0 (0,09) [†] | 0,9 (0,09) | 0,9 (0,9-1,0) [†] |
| MM (kg) | 64,6 (59,4-71,8) | 46,1 (40,2-52,3) [†] | 54,0 (12,8) | 50,8 (41,1-59,8) | 42,9 (37,5-55,6) | 55,3 (46,5-64,8) [†] | 54,2 (45,4-63,3) | 54,5 (43,7-64,7) |
| BF (%) | 25,7 (7,0) | 34,9 (6,2) [†] | 30,2 (7,9) | 34,6 (7,3)* | 24,6 (8,7) | 32,5 (6,9) [†] | – | – |
| SBP (mmHg) | 130 (120-140) | 120 (110-130) [†] | 120 (110-130) | 130(120-140) [†] | 115 (110-120) | 123 (120-140) [†] | 120 (110-130) | 130 (120-140) [†] |
| DBP (mmHg) | 80 (80-90,) | 80(70-80) [†] | 80 (70-85) | 80,0 (80-86) | 71 (70-80) | 80 (80-90) [†] | 80 (70-80) | 80 (80-90) [†] |
| Urea (mg/dL) | 33,0 (25,5-39,0) | 28,5 (23,0-36,0)* | 28,0 (24,0-36,0) | 39,0 (31,0-44,5) [†] | 26,0 (23,0-34,8) | 32,0 (25,0-38,0)* | 26,5 (24,0-34,0) | 30,0 (24,0-38,8)* |
| Ferritin (mg/mL) | 192,7 (108,8-293,5) | 56,7 (25,5-115,0) [†] | 70,8 (33,7-183,8) | 138,7 (79,2-207,4)* | 68,7 (26,6-150,3) | 98,0 (46,1-198,4) | 75,7 (22,8-195,4) | 115,9 (46,6-201,6) |
| Creatinine (mg/dL) | 1,0 (0,9-1,1) | 0,8 (0,7-0,8) [†] | 0,9 (0,7-1,0) | 0,9 (0,8-1,0)* | 0,9 (0,8-1,0) | 0,9 (0,7-1,0) | 0,9 (0,7-1,0) | 0,8 (0,7-0,9) |
| Uric Acid (mg/dL) | 30,0 (23,8-36,3) | 23,0 (19,0-30,0) [†] | 29,9 (21,0-34,0) | 23,5 (21,0-31,0) | 26,5 (21,0-33,8) | 25,0 (21,0-33,8) | 25,0 (20,0-34,0) | 25,0 (21,0-34,0) |
| Glucose (mg/dL) | 94,0 (87,0-110,5) | 89,0 (81,8-101,3) [†] | 89,0 (82,0-99,5) | 105,0 (92,0-144,0) [†] | 85,0 (78,0-97,0) | 93,0 (86,0 -107,0) [†] | 86,0 (78,5-93,5) | 95,0 (87,8-108,0) [†] |
| Insulin (UI/mL) | 8,3 (5,6-14,5) | 9,9 (6,5-13,8) | 9,0 (5,6-14,2) | 9,0 (6,6-13,6) | 5,2 (3,5-8,7) | 10,9 (7,3-15,1) [†] | 7,7 (4,9-11,5) | 11,2 (7,20-15,9) [†] |
| HDL-C (mg/dL) | 39,0 (33,0-45,5) | 52,0 (43,6-61,0) [†] | 46,0 (37,0-56,0) | 43,6 (37,8-53,3) | 53,0 (40,3-64,3) | 44,0 (36,0-52,5) [†] | 47,5 (40,0-61,0) | 44,0 (36,0-53,6)* |
| LDL-C (mg/dL) | 117,0 (40,3) | 130,9 (36,3)* | 127,3 (38,1) | 114,5 (38,7)* | 128,3 (39,6) | 124,2 (38,2) | 134,5 (16,7) | 118,7 (94,9-150,8) |
| TC/HDL-C | 5,0 (1,4) | 4,3 (1,3) [†] | 4,7 (1,5) | 4,2 (1,4) | 4,1 (1,2) | 4,7 (1,5)* | 4,6 (1,4) | 4,7 (1,6) |
| TG (mg/dL) | 137,0 (93,0-211,5) | 119,0 (85,0-163,0)* | 128,5 (92,0-185,0) | 105,0 (91,0-170,0) | 126,0 (98,3-206,3) | 123,0 (89,5-178,3) | 115,1 (72,5-193,3) | 113,5 (90,0-150,3) |
| CRP (mg/dL) | 0,9 (0,4-3,0) | 2,6 (1,0-6,0)* | 1,5 (0,5-4,3) | 2,9 (0,4-5,2) | 1,0 (0,3-2,1) | 2,3 (0,7-4,8)* | 1,4 (0,5-3,1) | 3,1 (1,4-6,0)* |
| ALT (U/L) | 28,0 (22,0-38,0) | 18,0 (14,0-24,0) [†] | 24,0 (15,9-33,3) | 19,0* (15,0-24,0) | 18,5 (15,3-26,8) | 24,0 (15,9-33,0)* | 19,5 (14,0-29,5) | 24,0 (17,0-32,0)* |

*p < 0,05.

[†]p < 0,001.

Data presented as mean ± SD or median and quartiles (p25-p75), when appropriate. P values according to Student's t-test or Mann-Whitney test, when appropriate.

WC: waist circumference; WHR: waist-to-hip ratio; MM: muscle mass; BF: body fat; SBP: systolic blood pressure; DBP: diastolic blood pressure; HDL: high-density lipoprotein; LDL: low-density lipoprotein; TC/HDL ratio: total cholesterol/high-density lipoprotein ratio; TG: triglycerides; CRP: C-reactive protein; ALT: alanine aminotransferase. Adults: age < 60 years. Senior: age ≥ 60 years. Normal Weight: BMI < 25 and 27 kg/m² for adults and seniors. Overweight: BMI ≥ 25 and 27 kg/m² for adults and seniors. Normal BF: BF < 25% and 33% for women and men. High: ≥ 25% and 33% for women and men.

with Latin women reported that, after four months of intervention, the participants resulted with a greater knowledge of CVD symptoms and risk factors. In addition, their health improved, especially for their triglyceride concentrations and the prevalence of metabolic syndrome³⁶. Fernandes et al. (2014)³⁷ provided educational lessons involving activities and didactic materials in a health center in Hawaii to help develop practical lifestyle changing skills and, consequently, prevent CVD as well as promote a better health for their patients. The lessons addressed knowledge on CVD, physical activity performance, blood pressure control, cholesterol, diabetes, body weight, healthy food eating and smoking cessation. After twelve months, significant improvements were observed in the health patterns of the patients and in their knowledge and self-care toward chronic diseases. There was also a significant reduction in concentrations of total cholesterol and fasting glucose.

The second objective of this study was to present preliminary results from a PROCARDIO trial. Thus, patients of

the program had significant clinical-metabolic improvement after three months of nutritional counseling. Specifically, patients exhibited decreased body weight (diabetics, dyslipidemia), total adiposity (general sample) and abdominal adiposity (general sample) after three months of nutritional counseling. Another previous study³⁸ also found a significant body fat percentage decrease in overweight and obese individuals after an intervention based on caloric restriction and physical activity. This reduction can improve the health of an individual and consequently reduce disease risks in CVD and metabolic complications. Individuals with chronic diseases, such as diabetes, hypertension and dyslipidemia, are expected to reach an appropriate weight and improve blood pressure, glycemic and lipid levels, consequently reducing cardiovascular development risk³⁹.

Furthermore, high prevalence of dyslipidemia was still found in our sample (79.1%, n = 235). This may have occurred as a result of the disease diagnostic criterion since the laboratory presentation of dyslipidemia comprises four

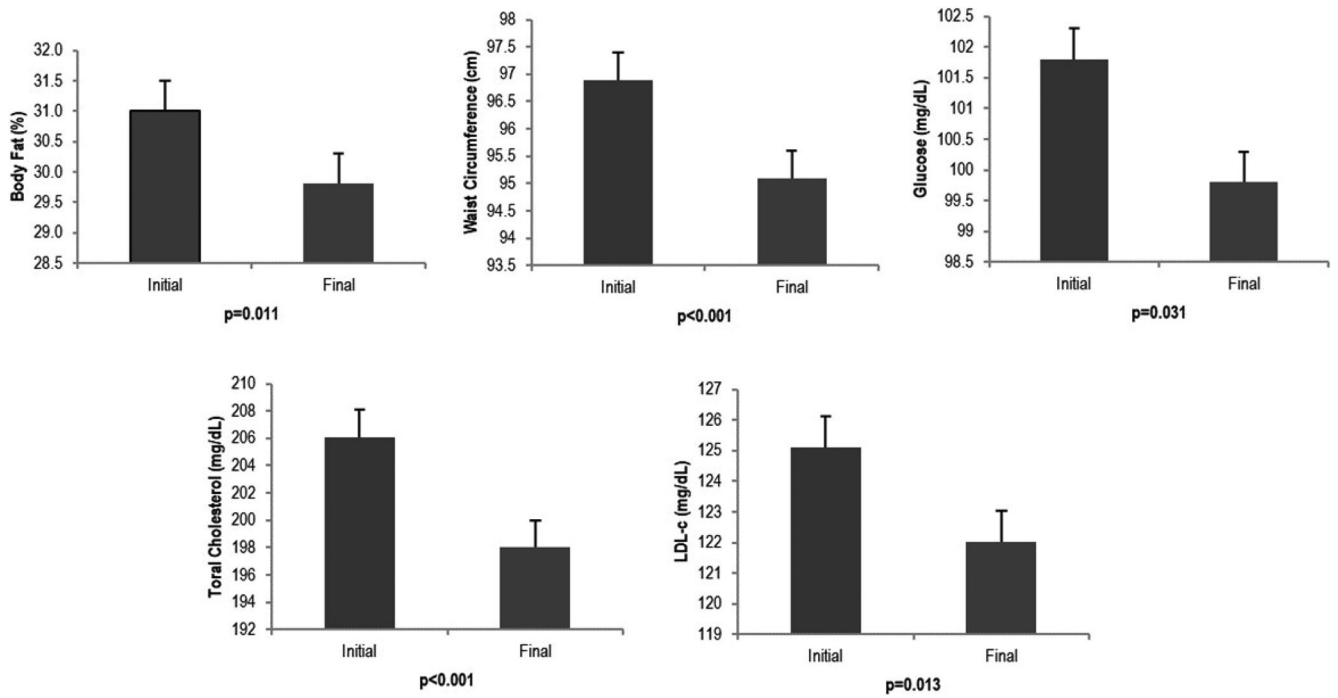


Figure 2. Change in anthropometric and metabolic indicators after three months of intervention in users (n = 296) of PROCARDIO. Data presented as mean ± SD. P values according to test t Pareado.

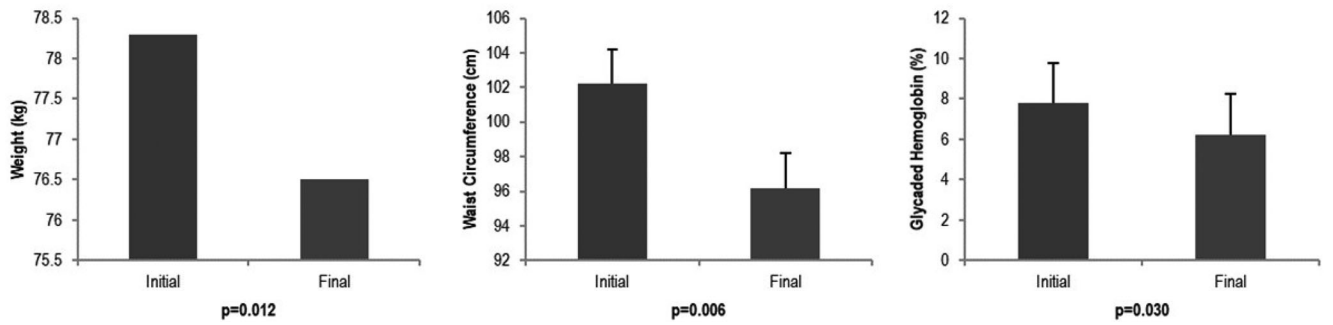


Figure 3. Change in cardiometabolic risk factors after three months of intervention in diabetic users (n = 54) of PROCARDIO. Data presented as mean ± SD. P values according to test t Pareado.

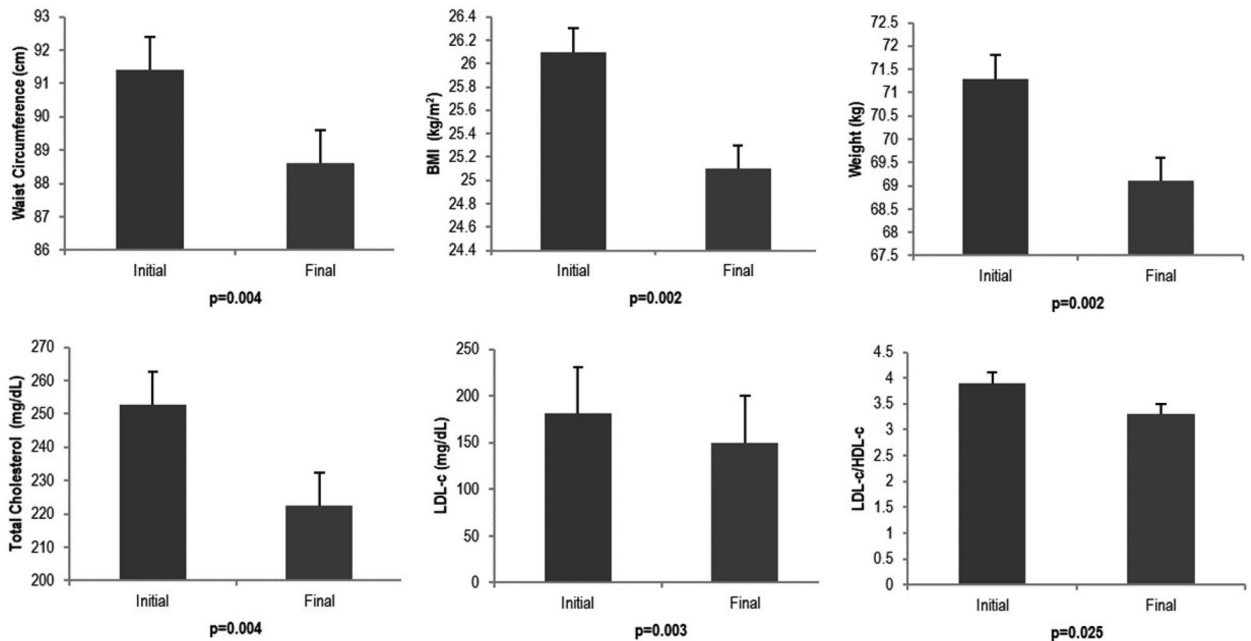


Figure 4. Change in cardiometabolic risk factors after three months of intervention in dyslipidemic users (n = 235) of PROCARDIO. Data presented as mean ± SD. P values according to test t Pareado.

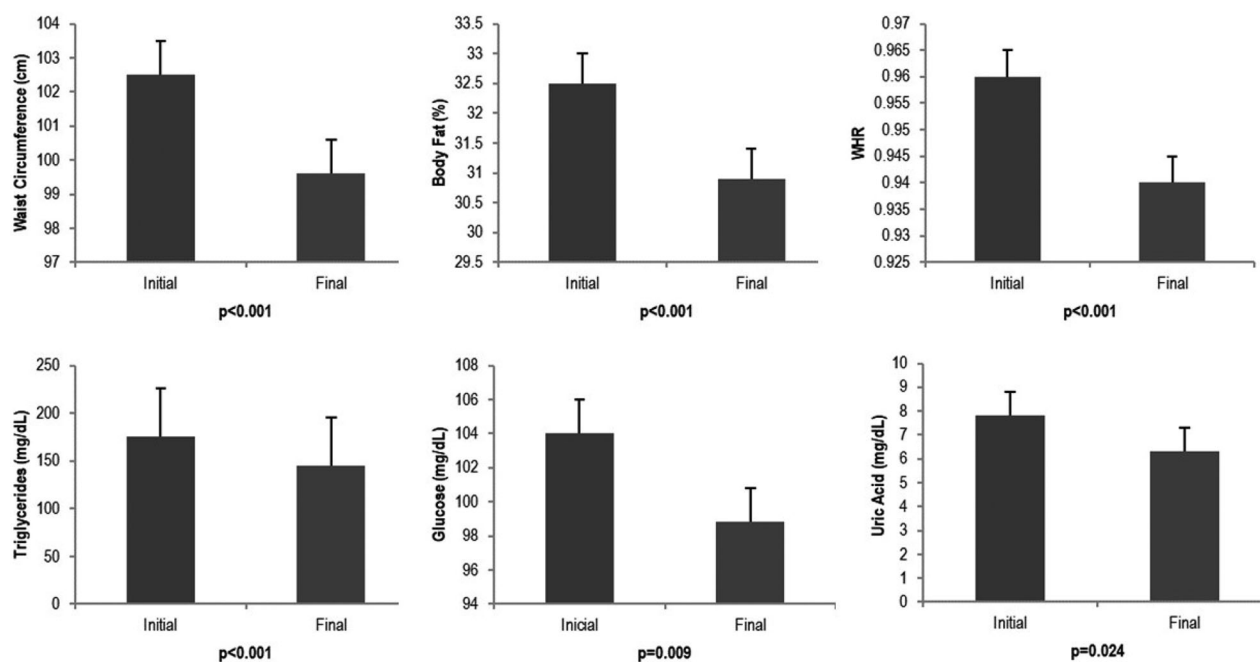


Figure 5. Change in cardiometabolic risk factors after three months of intervention in overweight ($n = 222$) users of PROCARDIO. Data presented as mean \pm SD or median and quartiles (p_{25} – p_{75}), when appropriate. P values according to test t Pareado or Wilcoxon.

well defined situations such as: isolated hypercholesterolemia: Isolated LDL-C elevation (≥ 160 mg/dl); Isolated hypertriglyceridemia: triglycerides isolated elevation (≥ 150 mg/dl); Mixed hyperlipidemia: Increased LDL-C (≥ 160 mg/dl) and triglycerides (≥ 150 mg/dl) and low HDL-C values: reduction of HDL-C (Men < 40 mg/dl and women < 50 mg/dl) isolated or in association the increase of LDL-C or TG²⁷.

Therefore, caloric and fat intake are dietary factors related to risk of dyslipidemia⁴⁰. Some lifestyle changes are recommended to control said chronic disease, such as weight control ($IMC < 25$ kg/m²), replacement of saturated fats by mono and poly-unsaturated fats and intake reduction of refined carbohydrates and simple sugars²⁷. The aforementioned changes are implemented and encouraged during the PROCARDIO program and many of our sample patients resulted with a significant decrease in the concentrations of total cholesterol, triglycerides and LDL-C after nutritional counseling.

Another important result of this study was significant reduction in glycated hemoglobin of diabetic individuals after receiving nutritional advice. It is noteworthy that glycated hemoglobin concentrations greater than 7% are associated with a higher risk of chronic complications, for example, polyneuropathy, diabetic retinopathy, and renal failure⁴¹. Furthermore, nutritional strategies for diabetes treatment include less caloric intake from fats, simple sugars and refined cereals, and increased fiber intake (integral grains, legumes, vegetables and fruits). Therefore, a decrease in glycated hemoglobin from 7.8% (± 2.4) to 6.3% (± 1.9) in diabetic patients after the nutritional counseling proved the importance of continuous nutritional strategies and lifestyle changes to control this variable and to further lessen future complications.

Ultimately, changes in food behavior is essential for clinical-metabolic and lifestyle improvement of individuals with CVD. At least one change in dietary patterns is expected (increased consumption of fruits and vegetables in and reduction in the intake of saturated fatty acids), though this result is not presented because food consumption data is being computed for further analysis.

Nonetheless, this study allows for some limitations because PROCARDIO does not have a control group to assess whether the actions developed within the program are effective. This program also has a convenience sample, contributing to patient interruptions and dropouts throughout the treatment, although the sample size is sufficient for statistical evaluation. However, our experience can provide important information on nutritional counseling approaches during the treatment of individuals with cardiometabolic risks. Finally, the scarcity of studies that approach a nutritional counseling methodology to be incorporated by health services with individuals of cardiometabolic risk factors limited the comparison of our results.

Conclusion

The individuals part of the PROCARDIO program presented a clinical-metabolic improvement after nutritional counseling, with a significant reduction in body fat percentage and waist circumference in overweight individuals, decreased glycated hemoglobin in diabetics and lipid profile improvement (reduction of total cholesterol, LDL-C and LDL-C/HDL-C) in patients with dyslipidemia patients. Our results therefore indicate the importance of nutritional strategies focused on personalized treatment and patient participation to reach proposed therapeutic goals.

Acknowledgments

We would like to thank PROCARDIO patients for participating in the study, as well as the professionals for their excellent technical assistance.

Disclosure statement

None.






Funding

Financial support was provided by the CAPES Foundation (Ministry of Education, Brazil), National Council for Scientific, Technological Development (CNPq/MCT/Brazil), and Foundation for Research Support of the State of Minas Gerais (FAPEMIG). HHM Hermsdorff is CNPq Research Productivity Fellowship. The funders had no role in the design, analysis or writing of this article.

Authors' contributions

Alinne Paula de Almeida: research design; obtaining data; data analysis and interpretation; writing of the manuscript; critical revision of the manuscript for important intellectual content. **Daniela Mayumi U. P. Rocha:** research design; obtaining data; analysis and interpretation of data and writing of the manuscript. **Ana Vlândia Bandeira Moreira:** critical review of the manuscript for important intellectual content. **Hatanne Carla Fialho e Moraes:** research design and data collection. **Helen Hermana Miranda Hermsdorff:** research design and critical review of the manuscript for important intellectual content.

ORCID

Alinne Paula de Almeida  <http://orcid.org/0000-0003-4158-8595>
 Daniela Mayumi Usuda Prado Rocha  <http://orcid.org/0000-0001-6130-0179>
 Ana Vlândia Bandeira Moreira  <http://orcid.org/0000-0001-6899-7378>
 Hatanne Carla Fialho Moraes e Lima  <http://orcid.org/0000-0001-5588-2002>
 Helen Hermana Miranda Hermsdorff  <http://orcid.org/0000-0002-4441-6572>

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